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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/618,596	07/17/2000	Robert A. Macina	DEX-0075	8607

7590 06/04/2002

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	19

DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/618,596	Applicant(s) MACINA ET AL.	
	Examiner Alana M. Harris, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *16* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 25, 2002 has been entered.

2. Claims 1-5 are pending.

Claims 1-3 have been amended.

Claims 1-5 are examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-5 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of Applicants' amendments to the claims.

5. The rejection of claims 1-5 under 35 U.S.C. 112, second paragraph, set forth in Paper numbers 10 and 12 (mailed April 5, 2001 and September 25, 2001, respectively) as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendments to the claims.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1-5 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Number 5,733,748 (filed June 6, 1995) and WO 96/39419 (Document AD on IDS) is withdrawn.

Grounds of Rejections

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 1-5 are vague and indefinite in the recitation "complement". It is not clear whether or not the complement should include several nucleic acid base pairs, partial-length or a full-length complement. Accordingly, the metes and bounds of the claims cannot be determined.

b. The recitation "hybridizing under stringent conditions" in claims 1-5 is vague and indefinite. The metes and bounds are unclear in the absence of limitations specifying specific stringency conditions.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. In anticipation of the instant rejection Applicants argue, "none of the 13 colon specific genes taught in the cited prior art reference exhibit[s] sufficient homology to the CSG of the present invention". Applicants also provide a definition of hybridization stringency and BLAST searches to support their arguments that the cited reference does not anticipate claims 1 and 2. These arguments are found unpersuasive.

Applicants' specification does not define the stringency conditions that set forth parameters (i.e. wash conditions) that limit what may or may not bind. Moreover the specification does not define of the term "complement". One of ordinary skill in the art would reasonably conclude that the bases of U.S. Patent 5,733,748 would bind the sequences designated below of Applicants' SEQ ID NO: 1.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,733,748 (filed June 6, 1995). U.S. Patent #5,733,748 discloses methods for diagnosing the presence of colon cancer and metastases of colon cancer in a patient (see Abstract; column 1, paragraph 1; bridging paragraph of columns 7 and 8). These methods are based on determining the levels of colon specific genes (CSG) in samples from a patient's cells, blood and saliva (see column 8, lines 30-32; column 9, lines 17-20), determining levels of a CSG comprising a polynucleotide sequence such as GCT (see columns 29 and 30, SEQ ID NO:1, nucleic acid residues 9-11 and 13-15 which are the same as residues 1-3 and 97-99) that would hybridize under stringent conditions with SEQ ID NO:1 and comparing the levels of CSG between colon cancer samples and non-diseased samples, see column 8, lines 10-16. It is the detection of active transcription, enhanced transcription or enhanced protein expression of a CSG in cells other than those derived from colon that is indicative of colon cancer metastases (column 8, lines 1-19). It is the Examiner's position that based on the disclosed methodology that it would be reasonable to conclude that clearly a patient with colon cancer had been identified. One of ordinary skill in the art would expect that the

detection of metastasis would be determined at a period after diagnosis in order to evaluate growth of the cancer.

The specification on page 9, lines 12-25 defines staging in effect as analyzation of a patient's sample for CSG, comparison between said sample and a normal control for an increase and decrease in levels of CSG. Monitoring colon cancer is defined utilizing the parameters set forth in staging in addition to periodic assessment of the cancer's growth (see "Monitoring" section of pages 9 and 10, particularly lines 19-22). Interpreted in light of the specification it is clear the disclosed method of the prior art which sets forth differentiating cancer and metastasis would read on Applicants' claims of staging, monitoring changes (i.e. regression and remission) and progression of the of the diagnosed colon cancer.

11. Applicants arguments have been set forth in the 102(e) rejection in anticipation of the instant rejection. The arguments are found unpersuasive.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/39419 (Document AD on IDS). WO 96/39419 discloses methods for diagnosing the presence of colon cancer and metastases of colon cancer in a patient (see Abstract; page 1, paragraph 1; page 14, paragraph 1). These methods are based on determining the levels of CSG in samples from a patient's cells, blood and saliva (see page 14, last paragraph; page 15, first paragraph; page 34, second paragraph), determining levels of a CSG comprising a polynucleotide sequence such as GCT (see Figure 1, first line, nucleic acid residues 9-11 and 13-15) that would hybridize under stringent conditions

with SEQ ID NO: 1 and comparing the determined levels of CSG between colon cancer samples and non-diseased samples, wherein if the transcription or protein expression is enhanced it is indicative of colon cancer metastases and inherently indicative of the presence of the said cancer (see page 14, paragraph 2). It is the detection of active transcription, enhanced transcription or enhanced protein expression of a CSG in cells other than those derived from colon that is indicative of colon cancer metastases. It is the Examiner's position that based on the disclosed methodology that it would be reasonable to conclude that clearly a patient with colon cancer had been identified. One of ordinary skill in the art would expect that the detection of metastasis would be determined at a period after diagnosis in order to evaluate growth of the cancer.

The specification on page 9, lines 12-25 defines staging in effect as analyzation of a patient's sample for CSG, comparison between said sample and a normal control for an increase and decrease in levels of CSG. Monitoring colon cancer is defined utilizing the parameters set forth in staging in addition to periodic assessment of the cancer's growth (see "Monitoring" section of pages 9 and 10, particularly lines 19-22). Interpreted in light of the specification it is clear the disclosed method of the prior art which sets forth differentiating cancer and metastasis would read on Applicants' claims of staging, monitoring changes (i.e. regression and remission) and progression of the of the diagnosed colon cancer.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
June 2, 2002